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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,273	02/11/2004	Jeff Rock Grandinetti	Grandi.J-01	5452

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PATENT LAW & VENTURE GROUP
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EXAMINER

BARHAM, BETHANY P

ART UNIT	PAPER NUMBER
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1615

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/777,273	Applicant(s) GRANDINETTI, JEFF ROCK	
	Examiner Bethany P. Barham	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/13/2004</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Summary

Receipt of IDS filed on 10/13/2004 is acknowledged. Claims 1-4 are pending.
Claims 1-4 are rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,683,719 ('719).

'719 teaches the limitations of claim 1-4:

- '719 teaches a composition comprising an active substance, particularly a biologically active substance, including pharmaceuticals, with a wide application in medicine including veterinary medicine and pharmaceutical dosage forms for human or animal use (col. 1, lines 35-45). '719 teaches that the extruded core

may be circular, elliptical or annular in cross-section, i.e. rods or hollow tubes with such rods or tubes having an external diameter of from 1 mm to 20 mm, preferably from 2 mm to 8 mm, and in the case of the hollow tubes an internal diameter of from ½ mm to 10 mm (col. 3, lines 55-62). Suitable lengths for the tubes or rods for human use is from 5 to 20 mm, whereas for animal use they may be correspondingly larger (col. 3, line 67-col. 4, line 2). '719 teaches that the hollow tubes can be coated and chopped to produce dosage forms in which the cut ends and interior surfaces of the tube are uncoated or coated with permeable material (col. 4, lines 45-50). '719 teaches that the extruded cores that are hollow tubes, wherein the hollow centre is filled by a second pharmaceutically acceptable material, that is preferably co-extruded and may be extruded of the kind of the present invention or of any other extrudable kind (col. 5, lines 17-22). The dry extrudates of '719 have a density of 1.5 to 3.0 gm/cc and appropriate force applied to cause extrusion (col. 4, lines 15-21 and 58-61).

- It is the Examiners opinion that a coated hollow tube chopped in half (to produce an open and a closed end), where the hollow center is then filled with an extruded pharmaceutically acceptable material is anticipated by '719. The size ranges of the diameter and lengths, as well as different density of extrudates resulting from the dye press of '719 dosage forms overlap with the instant claims 1-4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,895,662 ('662) in view of Remington's Pharmaceutical Sciences (1990).

The limitations of claims 1-4 are taught by '662 in view of Remington's:

- '662 teaches a hollowed pet treat for medicating a pet constructed entirely of an edible product and defining an interior space and an open top and a cap formed entirely of an edible product for being removably coupled to the open top of the vial for containing a predetermined medicine within the interior space (abstract). '662 teaches the height and width of the vial are equal and the length is three times, for example the vial may have a height of $\frac{1}{2}$ of an inch, a length of 1 and $\frac{1}{2}$ inches and a width of $\frac{1}{2}$ of an inch (col. 3, lines 45-49). '662 teaches a medicine capsule in a generally oval shape to be situated within the interior space of the vial.
- '662 does not teach a medicine that wedges into the interior space.
- Remington's teaches tablets that are discoid in shape, although they may be oval, oblong, round, cylindrical, or triangular, and their lower or upper surfaces may be flat, round, concave or convex to various degrees and their diameters

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range from 3/16 to 1/2 to 3/4 an inch (p. 1638 col. 1 and p. 1647 col. 1).

Remington's notes that veterinary tablets often have a bolus shape and are much larger than those used in medical practice (p. 1648 col. 1). Capsules are taught by Remington's to come in hard gelatin or soft elastic capsules (p. 1658 and p. 1662). Capsules are taught by Remington's to be supplied in a variety of sizes numbered from 000, the largest to 5, which is the smallest (p. 1658-1659).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '662 and Remington's to obtain a medicine that can be wedged in an edible capsule that is open at one end. One of ordinary skill in the art would be motivated to combine '662 and Remington's since both teach oral dosage forms for delivery to an individual and specifically teach how to formulate veterinary dosage forms. '662 teaches the edible capsule open at one end and closed at the other of the present invention except that its length is 1 1/2 inch in '662 where applicant claims 7/16 to 7/8 of an inch. As the MPEP 2144.05 states "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). One of ordinary skill in the art would know how to optimize the length of a pharmaceutical dosage form and the edible capsule through routine experimentation to obtain optimum workable ranges and would look to Remington's for how to do this.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)-272-6175. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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